

**COMBOsafe™ SURGICAL GOWNS**  
**SAFETY AND EFFECTIVENESS SUMMARY**

K041540

WORLD HEADQUARTERS  
ONE KNOLLCREST DR  
P.O. BOX 371805  
CINCINNATI, OHIO  
45222-1805513 761-9255  
513 761-0467 FAX  
1 800 999 0400

The following information is being supplied in accordance with the Safe Medical Device Act of 1990.

807.92(a)

1. Standard Textile Co., Inc.  
One Knollcrest Drive  
Cincinnati, Ohio 45237  
Contact Person: Brad Bushman  
(513) 761-9255 Ext. 455
2. Device Name: COMBOsafe™ Surgical Gowns (Europe)  
ProMax Surgical Gowns (US)  
Common/Usual Name: Non-Sterile Surgical Gown, Operating Room Gown, Isolation Gown  
Classification Name: Surgical Apparel 21 C.F.R. § 878.4040
3. All fabric components used in COMBOsafe™ Surgical Gowns are made from 100% polyester, dyed blue and/or green and are laminated with a urethane film.  
  
COMBOsafe Surgical Gowns will function as surgical gowns when processed according to instructions through 75 complete wash, dry and sterilization cycles. These products will be manufactured and distributed as non-sterile surgical gowns that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.
4. COMBOsafe Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect them by inhibiting the migration of liquids through the surface of the critical areas of the gown. Per ANSI/AAMI PB70:2003, COMBOsafe surgical gowns with the patented "inverted" 2-ply sleeve designs are classified as a Level 4 Barrier.
5. The tests that have been successfully completed include:
  - a. Flammability 16 CFR Part 1610.
  - b. Barrier Performance
    - i. Suter Hydrostatic Testing AATCC #127-1989
    - ii. Mullens Hydrostatic Testing ASTM D751-95 Procedure A
    - iii. Viral Resistance Testing ASTM 1671-97
  - c. Strength ASTM #D-1682-87
  - d. Lint EDANA 220.0-96
  - e. Toxicity - Cytotoxicity MEM Elution (MG023)  
Acute Systemic Toxicity (ISO 10993)
  - f. Primary Skin Irritation (ISO 10993)
  - g. Sterilization - Product sold non-sterile; can be sterilized using prevacuum steam cycles.
  - h. Durability through 75 processing (wash, dry and sterilization).
  - i. Colorfastness to Commercial Laundering - AATCC #61-1993(4A).

To the best of my knowledge, all data and information in the 510(k) are truthful and accurate, and that no material fact has been omitted.

 6/4/04  
Bradley J. Bushman



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 5 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Bradley J. Bushman  
Vice President, Technical Affairs  
Standard Textile Company Limited  
One Knollcrest Drive  
Cincinnati, Ohio 45237

Re: K041540  
Trade/Device Name: COMBOsafe/Promax Surgical Gowns  
Regulation Number: 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: II  
Product Code: FYA  
Dated: April 28, 2005  
Received: April 29, 2005

Dear Mr. Bushman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): #K041540

Device Name: COMBOsafe/Promax Surgical Gowns

### Indications For Use:

COMBOsafe/Promax Surgical Gowns are medical devices that are intended to be worn by operating room personnel during surgical procedures to protect them by inhibiting the migration of liquids through the surface of the critical areas of the gown.

COMBOsafe/Promax Surgical Gowns will function as surgical gowns when processed according to instructions through 75 complete wash, dry and sterilization cycles. These products will be manufactured and distributed as non-sterile surgical gowns that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

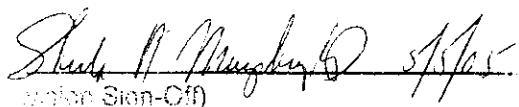
Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Official Sign-Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K041540